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WHITE, E EXAMINER

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

This application has been examined Responsive to communication filed on 12-13-1993 This action is made final.

A shortened statutory period for response to this action is set to expire three month(s), day(s) from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. Notice of References Cited by Examiner, PTO-892.
2. Notice re Patent Drawing, PTO-948.
3. Notice of Art Cited by Applicant, PTO-1449.
4. Notice of Informal Patent Application, Form PTO-152.
5. Information on How to Effect Drawing Changes, PTO-1474.
6. _____

Part II SUMMARY OF ACTION

1. Claims 1-6, 8-11, 13-15, 17, 18, 22-24, 27-32, 40-45, 48-51, 54-58 and 62-78 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. Claims _____ have been cancelled.

3. Claims _____ are allowed.

4. Claims 1-6, 8-11, 13-15, 17, 18, 22-24, 27-32, 40-45, 48-51, 54-58 and 62-78 are rejected.

5. Claims _____ are objected to.

6. Claims _____ are subject to restriction or election requirement.

7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. Formal drawings are required in response to this Office action.

9. The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are acceptable, not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been approved by the examiner, disapproved by the examiner (see explanation).

11. The proposed drawing correction, filed on _____, has been approved, disapproved (see explanation).

12. Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no. _____; filed on _____

13. Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. Other

SN - 08/166, 658

PTOL-326 (Rev. 9-89)

EXAMINER'S ACTION

Claims 1-6, 8-11, 13-15, 17, 18, 22-24, 27-32, 40-45, 48-51, 54-58 and 62-78 are pending in the instant application.

5 The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

10 A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which 15 the invention was made.

20 Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

25 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not 30 commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

35 Claims 1-6, 8-11, 13-15, 17, 18, 22-24, 27-32, 40-45, 48-51, 54-58 and 62-78 are rejected under 35 U.S.C. § 103 as being unpatentable over Willemse (US Patent No. 4,973,682) and Volpenhein (US Patent No. 4,517,360) in view of Osipow et al (US Patent No. 3,644,333), Yamagishi et al (JP 51-14486), Willemse (EPO 349059), Balint et al (US Patent No. 3,689,461), Balint et al (US Patent No. 3,679,368), Setzler (US Patent No. 3,567,369)

and Mansour (US Patent Nos. 4,449,828 and 4,472,061).

Applicants claim a continuous process for preparing highly esterified polyol fatty acid polyester by interesterifying polyol containing more than four esterifiable hydroxy groups and fatty acid ester of an easily removable alcohol in a heterogeneous reaction mixture wherein (a) a catalyst is used in the reaction mixture at an initial level of from about 0.01 to about 0.5 mole of catalyst per mole of polyol; (b) a soap emulsifier is used in the initial stage of the process at a level of from about 0.001 to about 0.6 mole of soap per mole of polyol; (c) the molar ratio of total ester reactant to each esterifiable hydroxy group of the polyol in the reaction mixture ranges from about 0.9:1 to about 1.2:1; (d) the temperature in the initial stage of the process ranges from about 130°C to about 140°C, and in the final stages of the process ranges from about 80°C to about 120°C; and (e) easily removable alcohol is removed from the reaction mixture as the interesterifying reaction proceeds.

The Willemse Patent discloses a process for the synthesis of polyol fatty acid polyesters comprising a two-stage transesterification of polyol to polyester. Willemse discloses a process wherein a substantially solvent-free complete reaction mixture of a polyol, optionally in admixture with fatty acid oligoesters thereof, fatty acid lower-alkylester, a transesterification catalyst, and optionally an emulsifier, is caused to react under transesterification conditions of elevated

temperature and reduced pressure, said pressure being controlled such that in an initial stage (1) said polyol is esterified to a degree of conversion within the range of 10 to 50% substantially without leaving non-participating polyol, and in a subsequent 5 final stage (2) the reaction is caused to proceed to a degree of conversion of at least 70%. The Willemse Patent further discloses a molar ratio of fatty acid lower-alkylester:sucrose within the range of from 10:1 to 20:1 (see column 4, lines 39-41) and a molar ratio of catalyst:polyol from 0.05:1 to 1:1 (see 10 column 4, lines 54-56). Willemse also discloses the use of alkali metal soaps having 6-12 carbon atoms (see column 4, line 67 to column 5, line 8). Willemse discloses that both stages of the transesterification reaction can be carried out at a similar temperature which normally lies within the range of from 100° to 15 180°C (see column 3, lines 50-52). In view of the difference in pressure regime during the initial and final stage of the reaction, Willemse discloses that it may be of advantage to use a reaction system comprising two separate reaction vessels each equipped with pressure control means optimized to the specific 20 reduced pressure regime needed (see column 3, line 62-67). The process by Willemse also involves removal of the lower-alkyl alcohol from the reaction mixture during the esterification reaction. Willemse also suggests that the process can be carried 25 out in a continuous or semi-continuous operation (see column 5, lines 64-68).

Volpenhein discloses a transesterification process for synthesizing polyol fatty acid polyesters comprising the steps (1) heating a mixture of (a) a polyol selected from the group consisting of monosaccharides, disaccharides and sugar alcohols, 5 (b) a fatty acid ester selected from the group consisting of methyl esters, 2-methoxy ethyl esters, benzyl esters and mixtures thereof, (c) an alkali metal fatty acid soap, and (d) a basic catalyst, to a temperature of from about 110° C to about 180° C at a pressure of from about 0.1 mm to about 760 mm of mercury to 10 form a homogenous melt; and (2) subsequently adding to the reaction product of step (1) excess fatty acid ester selected from the group consisting of methyl esters, 2-methoxy ethyl esters, benzyl esters and mixtures thereof (see column 2, lines 40-60). Volpenhein discloses that the heterogeneous mixture used 15 to carry out the process of step 1 generally comprises from about 10% to about 50%, preferably from about 15% to about 30%, by weight of the polyol; from about 40% to about 80%, preferably from about 55% to about 75%, by weight of the fatty acid esters; from about 1% to about 30%, preferably from about 5% to about 20%, by weight of the alkali metal fatty acid soap; and from about 0.05% to about 5%, preferably from about 0.1% to about 0.5%, by weight of the basic catalyst component (see column 5, lines 3-12). The process disclosed by Volpenhein is within the scope of the process set forth in the instant claims. Volpenhein 25 teaches heating the reaction mixture in the initial stages to

temperatures ranging from about 110° C to about 180° C (see column 5, lines 33-35), and teaches heating this reaction mixture in the final stages to temperatures of from about 120° C to about 160° C (see column 5, lines 53-57). The temperature range of 5 Volpenhein's initial stage covers the initial stage temperature range claimed by the Applicants and the final stage temperature of 120° C as disclosed in the Volpenhein reference is within the final stage temperature ranged claimed by the Applicants which is a maximum of 120° C.

10 Osipow et al, who also disclose a process for synthesizing sucrose esters, further disclose that the reaction between sucrose and the ester of a 12 to 22 carbon atom fatty acid occurs between the ester and solid sucrose having a very fine particle size, that is, in the magnitude of less than one micron in 15 diameter, in the presence of an alkaline catalyst (see column 4, lines 5-9) which appears to be within the scope of the instant claimed process.

The Japanese Laid-Open Patent Application 51/14486 shows that preparation of powder sugar using a conventional grinder, 20 i.e., by mechanical size reduction, is well known in the art.

Willemse (EPO) discloses a process for the synthesis of polyol fatty acid polyesters, in which a polyol and/or a fatty acid oligoester thereof, is esterified by reaction with fatty acid lower alkylester under substantially solvent free conditions 25 at elevated temperature in the presence of a transesterification

catalyst and, optionally an emulsifier, and in which at least during the final stage of the transesterification reaction the reaction mixture is submitted to the action of a stripping agent suitable for accelerating the removal of the lower alkyl alcohol formed in said reaction.

In general, the applicable law is that it does not involve patentable invention to merely claim the operation of an old process on a continuous basis. See, e.g., In re Lincoln, 126 F.2d 477, 478 (CCPA 1942) ("Merely operating the old process in a continuous manner is not seen to impart invention in the absence of a showing of unexpected beneficial results.") Accord, Ex parte Beeber, 123 USPQ 221, 223 (Bd. App., 1959). Claim 1 describes no particular features that are unexpectedly needed in a continuous process. The claim is therefore unpatentable for obviousness over the Volpenhein reference under 35 USC §103.

The Balint reference (US 3,6899,461) discloses a process for the preparation of linear condensation polyesters from a polycarboxylic acid and a polyol which can be carried out in a continuous or discontinuous process. The diagrammatical drawing of the apparatus used in Figure 1 suggests a process whereby the reaction is carried out under plug flow conditions by feeding the output of the initial stage into a series of at least two continuous stirred tank reactors. Example two of the Balint reference, which refers to Figure 1, describes a process whereby part of the partially esterified material which is produced is

returned to the inlet of the circulating pump to be combined with fresh paste, which appears to be within the scope of the backmixing step claimed in the instant application.

Balint et al (US Patent No. 3,679,368), Setzler and Mansour (US Patent Nos. 4,449,828 and 4,472,061) all show that the preparation of products in a continuous operation under conditions of backmixing and plug flow is well known in the art.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Willemse and Volpenhein's process for preparing polyol fatty acid polyesters by applying the various conditions under which the process is to be carried out as suggested by the Osipow et al and Yamagishi et al references which teach using solid sucrose of very fine particle size, Willemse (EPO) who teaches a transesterification process and the removal of alcohols, Balint et al (US Patent No. 3,689,461), Balint et al (US Patent No. 3,679,368), Setzler and Mansour who all teach carrying out a process in a continuous operation and under conditions of backmixing and plug flow, since such process steps for preparing polyol polyester and such conditions for the operation of a continuous process are well known in the art.

Claims 63-78 are rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Feuge et al (US Patent No. 3,714,144) and Feuge et al ("Preparation of Sucrose Esters By

Interesterification," Journal of the American Oil Chemists' Society, Vol. 47, pp. 56-60 (1970) in view of Volpenhein (US Patent No. 5,518,772), Rizzi et al (Rizzi and Taylor, "A solvent-Free synthesis Of sucrose Polyesters," Journal of the American Oil Chemist's Society, Vol. 55, pp. 398-401 (1978), McCabe and Smith (Unit Operations of Chemical Engineering), and Felder et al (Elementary Principles of Chemical Process).

Applicants claimed a process for the synthesis of polyol fatty-acid polyesters by reacting a polyol and a fatty-acid lower-alkyl ester under substantially solvent free conditions in the presence of a catalyst and an emulsifier, the process comprising: an initial reaction stage which is carried out under such conditions that the reaction mixture in said initial stage is in steady-state, with continuous introduction of reactants comprising polyol and fatty-acid lower-alkyl ester, and continuous removal of the products comprising reaction mixture having a degree of esterification of about 10% or more and volatile alcohol formed during the initial reaction stage; and one or more subsequent reaction stages in which the reaction mixture from said initial stage is further reacted to said polyol fatty-acid polyesters.

Both Feuge et al references disclose processes which involve the reaction of sucrose with fatty acid esters under solvent-free conditions. The Feuge et al Patent relates to the production of sucrose esters of fatty acids and more specifically to making

mono-, di- and higher esters of sucrose (see column 1, lines 30-33). The Feuge et al Patent teaches that the fatty acids are employed in the form of esters and the Patent exemplifies methanol and glycerol esters. Among the glycerol esters are said 5 to be monoglycerides, diglycerides and mixtures of mono-, di-, and triglycerides (see column 6, lines 39-47). The Feuge et al patent also recognizes the need for both a catalyst and an emulsifier and uses the same composition for both functions (see column 4, lines 66-68). The Feuge article illustrates the same 10 process as the Feuge patent.

The Feuge Patent further teaches that its reaction is carried out in two stages. In the first stage, carried out at atmospheric pressure under an inert atmosphere of nitrogen, the reaction mixture is heated to about 185° C and held and mixed at 15 this temperature for a short period of time sufficient to melt or dissolve the reactants and produce a fluid, uniform mass. The phase is said to require between 4 and 20 minutes (see column 3, lines 41-61). See also, the Feuge et al article at page 57, first paragraph under heading "Melting of Sucrose" and page 59, footnote to Table II. In the second phase of the reaction, the output from the first phase is subjected to vacuum heating at a partial pressure of 1 to 10 mm and a temperature of 170 to 185° C. Heating under vacuum is continued for 2 to 10 minutes during 20 which time the original mono- or polyhydric alcohol formed during 25 the reaction is removed by distillation.

The Feuge et al Patent also teaches that the process can be operated in a continuous manner (see from column 3, line 73 to column 4, line 17). It is well accepted in the art that any process that is continuous must operate in "steady state" and be mass balanced except during start-up (see, e.g., Elementary Principles of Chemical Processes by Felder et al (Wiley 1978), page 82. There a "continuous" process is defined as one in which "the inputs and outputs flow continuously through the duration of the process." The Felder et al text goes on to explain that if all the variables in a process do not change with time except for minor fluctuations about constant mean values, "the process is said to be operating at steady state." Moreover, the text explains that "continuous processes are actually run as close to steady state as possible" except "during the start-up of a process and following changes ... in process operating conditions."

It is further understood in the art that when a process is in steady state during continuous operation, the quantity of material entering the reaction zone must equal the quantity leaving the reaction zone, i.e. there must be what is referred to as a mass balance (see, e.g., Unit Operations of Chemical Engineering, 3rd Ed. by McCabe and Smith, (McGraw-Hill, 1976) at page 66.

In light of the Feuge teachings of the specific reaction and its degree of conversion in the initial stage, the teachings in

the Feuge et al Patent that the process can be carried out on a continuous basis is a teaching that the process and each stage of the process can and should be carried out under steady state conditions with mass balance of incoming and outgoing streams of reactants and reaction products.

5 In general, the applicable law is that it does not involve patentable invention to merely claim the operation of an old process on a continuous basis. See, e.g., In re Lincoln, 126 F.2d 477, 478 (CCPA 1942) ("Merely operating the old process in a 10 continuous manner is not seen to impart invention in the absence of a showing of unexpected beneficial results.") Accord, Ex Parte Beeber, 123 USPQ 221, 223 (Bd. App., 1959).

Both Lincoln and Beeber involved situations where the references did not expressly teach that the prior art batch 15 process could be carried out in a continuous operation. Here, however, the Feuge et al Patent does expressly teach that the batch esterification process can be carried out in a continuous operation. And claim 63 describes no particular features that are unexpectedly needed in a continuous process. It merely 20 recites the "mass balance" and "steady state" parameters which are necessarily inherent in any continuous process. Consequently, claim 63 in reciting steady state and mass balance merely specifies a continuous process. The claim is therefore unpatentable for obviousness over the Feuge et al references 25 under 35 USC §103.

To the extent that claim 63 is unpatentable because of obviousness under 35 U.S.C. §103, the additional limitations in the dependent claims discussed below do not include any features that would render the claims non-obvious.

5 Claim 65 of the instant application specifies that the emulsifier be an alkali metal soap. Claim 66 specifies that the alkali metal soap be a soap having from 8 to 22 carbon atoms. The Feuge et al Patent discloses that "sodium oleate was used as a catalyst and emulsifier" which is analogous to claim 65. The 10 Volpenhein '772 Patent discloses that emulsifiers in this process will generally be fatty acid soaps having from 8 to 18 carbon atoms (see col. 4, lines 8-9). Nothing in the Feuge et al references suggests the criticality of the oleate species. In view of Volpenhein '772, it would be obvious that other fatty 15 acid moieties could be substituted for the oleate.

Claim 67 of the instant application specifies that the fatty acid lower-alkyl ester be a fatty-acid methyl ester. The Feuge et al Article teaches the use of methyl palmitate. (see last two lines of page 58). See also the Feuge et al Patent at column 7, 20 lines 4-11.

Claim 70 of the instant application claims that the reaction mixture in the initial stage does not contain any substantial amount of solvent. The Feuge et al article in the second sentence of its "Abstract" specifically points out the 25 interesterification process is "solvent free." The "abstract" of

the Feuge et al Patent also specifies that the reaction is carried out "without solvent."

Claims 73 and 74 of the instant application specify molar ratios of respectively transesterification catalyst to polyol 5 (0.01:1 to 0.5:1) and of emulsifier to polyol (0.2:1 to 0.6:1) in the initial stage. The Feuge et al references teach a molar ratio of sodium oleate to sucrose that is below "about 40% based on the weight of sucrose employed" and "could well be below 10%" (see, e.g., Feuge et al Patent, column 5, lines 24-30). This 10 corresponds to about 0.11:1 to 0.45:1 on a molar ratio basis (See Appendix A hereto which shows how the molar ratio used by Feuge et al is ascertained). Thus the molar ratios are within the limitations of claims 73 and 74.

Claim 76 of the instant application specifies that the 15 polyol be sucrose. In their respective titles and in their disclosures, the Feuge et al references deal only with preparing esters of sucrose.

Claim 77 of the instant application requires that the molar ratio of fatty acid lower alkyl ester to sucrose be from 7.2:1 to 20 15:1. The Feuge et al Patent teaches specifically that for more highly acylated sucrose, the ratio of sucrose to lower ester should be "much lower" than 1:1 (see column 7, lines 20-30). This corresponds to a ratio of lower ester to sucrose "much higher" than 1:1. It was well known in the art that in making 25 polyesters, the ratio of fatty acid methyl ester to sucrose

should be about 12:1. See, e.g., Volpenhein '772, column 6, lines 35-36 (mole ratio of 12:1) and the Rizzi article, page 399, last line (mole ratio 11.8:1).

Claim 78 of the instant application requires that the process of claim 63 be carried out such that the initial reaction stage is fully separate from the subsequent reaction stages. In the Feuge et al Patent, at col. 3, lines 40-57 and in Example 1, it is clear that the two zones are distinctly different. In Example 1, the Feuge patent shows that the reaction flask is immersed in an oil bath for 14 minutes and thereafter "transferred to a second oil bath..." (see col. 7, lines 50-57).

It would have been obvious to one having ordinary skill in the art at the time the invention was made having the Feuge et al Patent and Feuge et al Article before him to produce a process for preparing polyol fatty-acid esters which is operated in a continuous manner by reacting a polyol and a fatty-acid lower-alkyl ester under substantially solvent free conditions in the presence of a transesterification catalyst and an emulsifier whereby limitations which involve a continuous operation is further supported by the Felder et al and McCabe & Smith, the limitation which involves fatty acid soaps having from 8 to 18 carbon atoms is supported further in the Volpenhein reference and the ratio of fatty acid methyl ester to sucrose is further supported by Volpenhein and the Rizzi et al Article, since Felder et al, McCabe & Smith, Volpenhein and Rizzi et al show that such

limitations used in a process for preparing polyol fatty-acid esters are well known in the art.

Claims 63-78 are rejected under 35 U.S.C. § 103 as being unpatentable over Rizzi et al (Rizzi and Taylor, "A Solvent-Free Synthesis of Sucrose Polyesters," Journal of the American Oil the American Oil Chemist's Society, Vol. 55, pp. 398-401 (1978) and Galleymore (US Patent No. 4,298,730) in view of McCabe and Smith (Unit Operations of Chemical Engineering) and Felder et al (Elementary Principles of Chemical Process).

Applicants claimed a process for the synthesis of polyol fatty-acid polyesters by reacting a polyol and a fatty-acid lower-alkyl ester under substantially solvent free conditions in the presence of a catalyst and an emulsifier, the process comprising: an initial reaction stage which is carried out under such conditions that the reaction mixture in said initial stage is in steady-state, with continuous introduction of reactants comprising polyol and fatty-acid lower-alkyl ester, and continuous removal of the products comprising reaction mixture having a degree of esterification of about 10% or more and volatile alcohol formed during the initial reaction stage; and one or more subsequent reaction stages in which the reaction mixture from said initial stage is further reacted to said polyol fatty-acid polyesters.

The Rizzi article describes a two step process for making

sucrose fatty-acid esters, including sucrose lower esters (i.e., mono and diesters) and sucrose polyesters (see page 398, "Abstract") by reacting fatty-acid esters of methyl esters derived from soybean oil (see page 398, "Materials"), and a 5 transesterification catalyst of alkali metal hydrides or Na-K alloy (see page 398, "Abstract") under solvent free conditions (see page 398, "Abstract").

In the first stage, the Rizzi article discloses that sucrose, methyl esters, emulsifier and catalyst are treated at 10 reduced pressure and a temperature of approximately 150° C, "during which time all the sucrose appeared to dissolve." (see page 399, column 2, "Sucrose/ME/Sucrate Ion Reactions"). The "Abstract" at page 398 describes the resulting "one phase melt as containing mainly lower esters of sucrose." At page 399, column 15 2, these "lower esters" are shown to be mono- and di-esters.

In Rizzi's second stage, the first stage product is further reacted at a reduced pressure and a temperature of about 150° C with additional methyl ester (see page 399, "Sucrose/ME/Sucrate Ion Reactions"). The Rizzi article's data shows that the n , defined at page 398 as the "approximate degree of esterification in isolate SPE," for the second stage reaction product was as 20 high as 7.25 (see page 399: "Sucrose/ME/Sucrate Ion Reaction"). That 7.25 value corresponds to a 91% "polyol conversion" through Rizzi's two stages (In Appendix B hereto, it is shown how Rizzi's 25 value of $n = 7.25$ corresponds to a 91% "polyol conversion").

Although Rizzi et al does not show operation of the first stage in a continuous process, that feature would be obvious from the teachings of the Galleymore patent. Galleymore teaches that Rizzi et al first stage product, i.e. sucrose mono- and di-esters, can be made in a continuous transesterification process. Thus, at column 1, lines 5-7, the Galleymore patent teaches that it relates to "the production...of one or more fatty acid esters of sucrose," and, more specifically, to making "sucrose mono- and di-esters" (see column 3, line 55).

It is well understood in the art that a process is in "mass balance" when "the rate of mass entering the flow system equals that leaving." See, Unit Operations of Chemical Engineering 3d Ed. by McCabe and Smith, (McGraw-Hill, 1976) at page 66. Thus, when the Galleymore patent describes a first stage in which "fresh starting material can constantly be introduced into a through reactor...and the crude product can constantly be removed from the other end" (see column 6, line 67, through column 7, line 2) and "the product obtained can be continuously withdrawn from the reactor" (see column 7, lines 8-10), that can only be operated continuously if there is a mass balance. Any other situation would preclude a continuous operation either because of the reactor emptying out if the output exceeded the input or because of the reactors exploding or overflowing if input exceeded output.

It is further accepted in the art that any process that is

continuous is expected to operate in "steady state," except during start-up. See, e.g., "Elementary Principles of Chemical Process" by Felder et al (Wiley 1978) at page 82. There, a continuous process is defined as one in which "the inputs and outputs flow continuously through the duration of the process." The Felder et al text goes on to explain that if all the variables in a process do not change with time except for minor fluctuations about constant mean values, "the process is said to be operating at steady state." Moreover, the text explains that "continuous processes are actually run as close to steady state as possible" except "during the start-up of a process and following changes...in process operating conditions."

Galleymore discloses that his Example 10 was run as a "semi-continuous" procedure due to the "charge" of reactants and "discharge" of the product. But, then Galleymore explains at column 17, lines 63-65 that "true continuity would be achieved by gradual addition of the feedstocks and removal of the product formed." In context, this constitutes a direct teaching of a steady state process. As the Felder et al text shows, a process is operated at "steady state...if the values of all the variables in a process (i.e., all temperatures, pressures, volumes, flow rates, etc.) do not change with time."

Applying the conventional definition as reflected in the Felder et al text, Galleymore's Example 10 teaches what would necessarily be a 'steady state' process:

1. Temperature and pressure are constant during the reactions. Thus, the reactor is maintained at constant temperature in an oil bath at 130°C; the reaction mixture is maintained at 125°C; and in-going reactant is fed into the vessel 5 at 125°C, the same temperature as the product in the vessel. Pressure is constant because the vessel is maintained at atmospheric pressure.

2. The composition of the in-going reactant stream remains constant over time because the glyceride stock mixture is 10 homogeneous due to "vigorous stirring." The incoming stream has a constant ratio of sucrose, glyceride mixture and potassium methoxide because the entire reaction mixture is made up in one pot and aliquots of the mixture are fed into the reactor. And there would be a mass balance in what Galleymore says would be 15 "true continuity," i.e., "gradual addition of the feedstock and removal of the product."

In light of the Galleymore patent's teachings of a continuous transesterification process with reactants similar to the Rizzi article's first stage and yielding a reaction product 20 substantially the same as Rizzi's first stage reaction products, i.e., sucrose mono- and di-esters, it would have been obvious to persons skilled in the art to run the first stage of the Rizzi process in a continuous manner and to thereafter continue the reaction with Rizzi's second stage. Thus, the subject matter of 25 Claims 1 and 63 of the instant application would have been

obvious to persons skilled in the art and is thus unpatentable under 35 U.S.C. § 103.

To the extent that claim 1 is unpatentable because of obviousness under 35 U.S.C. §103, the additional limitations in 5 the dependent claims discussed below do not contain any saving features.

Claim 64 of the instant application specifies that any additional reactants are added to the initial stage product and further reacted in a subsequent stage. At page 398 of the 10 "abstract," the Rizzi Article teaches that "in the second stage more methyl esters are added." See also, page 398 of the "Sucrose/ME/Sucrate Ion Reaction" that teaches that in Rizzi's second stage "an additional 297.0 ml of methyl esters" are added to the first stage product and further reacted.

15 Claim 65 of the instant application specifies that the emulsifier be an alkali metal soap. Claim 66 specifies that the alkali metal soap be a soap having 8 to 22 carbon atoms. At page 398 of the Rizzi Article's "Abstract," the emulsifiers are said 20 to be "potassium soaps". Galleymore teaches at column 4, lines 31-48 that alkali metal soap emulsifiers including potassium soap "should contain an acid moiety with at least 8 carbon atoms."

Claim 67 of the instant application requires the lower-alkyl ester to be a methyl ester. Rizzi et al use methyl esters.

25 Claim 68 of the instant application specifies that the transesterification catalyst be selected from the group of

potassium hydroxide and carbonates of potassium and sodium. At column 5, lines 40-45, the Galleymore patent teaches various transesterification catalysts including alkali metal carbonates.

Claim 70 of the instant application requires that the reaction mixture in the initial stage does not contain any substantial amount of solvent. At page 398 of the "Abstract", the Rizzi Article specifically points out that the process is solvent free. See also page 399 of Rizzi et al, "Sucrose/ME/Soap Reactions" which shows no solvent being used in the Rizzi et al process. The Galleymore patent, at column 3, line 60, also specifies that the reaction is carried out "in the absence of any solvent."

Claim 71 of the instant application specifies that the initial stage is maintained at a temperature of 120 to 140°C. At column 6, lines 42-50, the Galleymore patent teaches a temperature of 110°C to 140°C." See also, the Rizzi Article at page 399 of the "Sucrose/ME/Sucrate Ion Reactions" that shows a temperature of 145-148°C and then 150°C.

Claim 72 of the instant application specifies an average residence time of the reaction mixture of the initial stage to be about 1.5 hours. At column 7, lines 5-7, Galleymore says that "the residence time of the reaction mixture in the reactor can be as low as two hours."

Claims 73 and 74 of the instant application specify molar ratios of respectively transesterification catalyst to polyol

(0.01:1 to 0.5:1) and emulsifier to polyol (0.2:1 to 0.6:1) in the initial stage. The molar ratio of catalyst to sucrose in Example 10 of the Galleymore patent appears to be within the scope of the molar ratio of catalyst to polyol claimed in the instant application. The Rizzi Article at Table II, page 399, shows a molar ratio of potassium oleate (emulsifier) to sucrose between 0.25:1 and 0.5:1.

Claim 75 of the instant application specifies the synthesis of polyol fatty-acid polyesters of at least 70%. As shown in Appendix B hereto, the Rizzi Article's data shows a "polyol conversion" of about 91%.

Claim 76 of the instant application specifies that the polyol be sucrose. Both Galleymore and Rizzi et al teach the preparation of esters of sucrose.

Claim 77 of the instant application requires that the molar ratio of fatty acid lower alkyl ester to sucrose be between 7.2:1 to 15:1. The Rizzi Article specifically teaches a molar ratio of fatty acid lower alkyl ester to sucrose of 11.8:1 (see page 399, "Sucrose/ME/Soap Reactions").

Claim 78 of the instant application requires that the process of claim 63 be carried out such that the initial reaction stage is fully separate from the subsequent reaction stages. The Rizzi Article (page 399, left-hand column, "Sucrose/ME/Soap Reactions") discloses the initial reaction of sucrose, K-oleate and methyl oleate (first zone), followed by the addition of more

methyl oleate and gradually raising the reaction temperature (second zone).

It would have been obvious to one having ordinary skill in the art at the time the invention was made having the Rizzi et al article and Galleymore et al patent before him to produce a process for preparing polyol fatty-acid esters which is operated in a continuous manner by reacting a polyol and a fatty-acid lower-alkyl ester under substantially solvent free conditions in the presence of a transesterification catalyst and an emulsifier whereby limitations which involve the continuous operation is further supported by the Felder et al and McCabe & Smith reference since Felder et al and McCabe & Smith show that such limitations used in a process such as the preparation polyol fatty-acid esters are well known in the art.

15 Claims 1-6, 8-11, 13-15, 17, 18, 22-24, 27-32, 40-45, 48-51, 54-58 and 62-78 are rejected under 35 U.S.C. § 103 as being unpatentable over Rizzi et al ("A Solvent-Free Synthesis Of Sucrose Polyesters," Journal of the American Oil Chemists' Society, Vol. 55, pp. 398-401 (1978)) and Volpenhein (U.S. Patent No. 4,518,772) in combination with Takagishi (Japanese Patent Publication No. 50-135016) in view of European Patent Application No. 254,376, McCabe and Smith (Unit Operations of Chemical Engineering), Felder et al (Elementary Principles of Chemical Process), Levenspiel (Chemical Reaction Engineering, 2nd Ed. by

Levenspiel (Wiley & Sons, 1972) at pages 97-98).

Applicants claim a continuous process for preparing highly esterified polyol fatty acid polyester by interesterifying polyol containing more than four esterifiable hydroxy groups and fatty acid ester of an easily removable alcohol in a heterogeneous reaction mixture wherein (a) a catalyst is used in the reaction mixture at an initial level of from about 0.01 to about 0.5 mole of catalyst per mole of polyol; (b) a soap emulsifier is used in the initial stage of the process at a level of from about 0.001 to about 0.6 mole of soap per mole of polyol; (c) the molar ratio of total ester reactant to each esterifiable hydroxy group of the polyol in the reaction mixture ranges from about 0.9:1 to about 1.2:1; (d) the temperature in the initial stage of the process ranges from about 130°C to about 140°C, and in the final stages of the process ranges from about 80°C to about 120°C; and (e) easily removable alcohol is removed from the reaction mixture as the interesterifying reaction proceeds.

The Rizzi et al Article describes a two stage process for making sucrose fatty-acid esters, including sucrose lower esters (i.e., mono and diesters) and sucrose polyesters (see Abstract on page 398) by reacting fatty-acid esters of methyl esters derived from soybean oil (see subheading "Materials" on page 398), in the present of alkali metal soap emulsifier, and a transesterification catalyst of alkali metal hydrides or Na-K alloy under solvent free conditions. In the first stage, Rizzi et al disclose

that sucrose, methyl esters, emulsifier and catalyst are treated at reduced pressure and a temperature of approximately 150°C. In the second stage, the first stage reaction mixture is further reacted by adding additional fatty-acid lower alkyl esters to 5 achieve an over 90% yield of sucrose polyesters.

The Volpenhein Patent describes a two-stage process for making sucrose fatty acid polyesters by reacting fatty acid esters including methyl esters in the presence of a transesterification catalyst and a alkali metal fatty acid soap (see column 10 2, lines 41-59) under solvent free conditions (see column 2, lines 36-38). In Volpenhein's first stage, polyol [sucrose], fatty-acid soap [emulsifier] and catalyst are reacted at reduced pressure and a temperature from about 110°C to 180°C (see column 15 3, line 17 to column 4, line 22) to form a homogeneous melt comprising partially esterified polyol and unreacted starting materials (see column 3, lines 20-22), with a lower alcohol formed as the transesterification reaction proceeds (see column 5, lines 44-54). In Volpenhein's second stage, the homogeneous melt comprising partially esterified polyol and unreacted 20 starting material from the first stage is further reacted at a reduced pressure and a temperature between about 120°C to 160°C with additional fatty acid lower alkyl esters (column 5, lines 25-43).

Rizzi et al and Volpenhein each describe first stage 25 reactions of sucrose and a fatty acid ester in a solvent-free

method to produce partial sucrose fatty acid esters in a batch process using soap emulsifiers. Takagishi teaches that the identical reaction to make partial sucrose fatty acid esters can and preferably should be carried out in a continuous process and 5 should preferably use a different emulsifier rather than soap. Takagishi explains that before his invention, sucrose fatty acid esters were made by reaction in a solvent-free method between sucrose and a fatty acid ester in the presence of a fatty acid soap (see page 3 of the translated copy of the Takagishi 10 Reference).

Takagishi teaches "a method for producing sucrose fatty acid esters wherein the sucrose fatty acid esters are nonionic surfactants that are useful as edible dispersants, emulsifying agents, detergents or the like" (see translation, page 3). Rizzi et al teaches that the sucrose esters that are known in the art 15 as surfactants and emulsifiers in food systems are the mono or partially acylated sucrose esters (see Rizzi et al at page 398, left column). Volpenhein teaches that the first stage reaction product comprises partially esterified polyol, e.g. sucrose (see 20 column 3, line 20). Takagishi's Practical Example 1 confirms that Takagishi's sucrose fatty acid ester comprises partial sucrose fatty acid esters. There, Takagishi describes one particular sucrose fatty acid ester as containing 50 wt. % monostearate and monopalmitate and 50 wt % di- and tristearate 25 and di and tripalmitate. Page 12 of the Takagishi translation

shows some additional partial fatty acid esters of sucrose as sucrose fatty acid esters compositions. Since partial sucrose esters of fatty acids means an average of at most 4 hydroxyl groups esterified with fatty acid (see page 2, lines 8-11 of European Patent Application No. 254,376), Takagishi's mono-, di- and tri-esters clearly are partial sucrose esters of the type contemplated as the product from Rizzi et al's and Volpenhein's first stages.

Takagishi further teaches that its process, which is clearly intended to make products like those made in Rizzi et al's and Volpenhein's respective first stages, can be and preferably is operated in a continuous manner (see page 6 of the translated copy). It is well understood in the art that any process that is continuous is expected to operate in "steady state," except during start-up. See, e.g., "Elementary Principles of Chemical Process" by Felder et al (Wiley 1978) at page 82. It is further accepted in the art that when the process is in steady state during continuous operation, the quantity of material entering the reaction zone must equal the quantity leaving the reaction zone, i.e. there must be what is referred to as "mass balance" (see Unit Operations of Chemical Engineering 3rd Ed. by McCabe and Smith, (McGraw-Hill, 1976) at page 66).

Takagishi teaches to one of ordinary skill in the art that a process for producing partial sucrose fatty acid esters in a continuous manner as described by Takagishi "is more effective"

than batch methods (such as that shown by Rizzi and by Volpenhein) because "the reaction rate was greatly increased, and problems such as coloration of the reaction fluid and sucrose cohesion were completely prevented" (see Takagishi translation at 5 pages 4 and 6). Thus, one reading Takagishi would clearly be taught to replace the batch method of Rizzi et al's and Volpenhein's first stage with Takagishi's "more effective" continuous process. Takagishi teaches how such a continuous process is performed and thus, demonstrates a reasonable 10 likelihood of success for operating Volpenhein's and Rizzi et al's first stage in a continuous manner. Hence, the process of the instant application is *prima facie* obvious. See Merck and Co. Inc. v. Biocraft Laboratories Inc., 10 USPQ2d 1847 (obviousness, under 35 U.S.C. §103, is found where "the prior art 15 would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in light of the prior art."

Apart from continuous operation, Takagishi's reactants and process conditions are otherwise the same as those used by Rizzi 20 et al's and Volpenhein. Volpenhein's first stage, Rizzi et al's first stage and Takagishi's processes all use the same reactants, i.e. sucrose and methyl esters of fatty acid, to make the same products, i.e. partial sucrose fatty acid esters. For sucrose, see, Volpenhein at column 3, lines 50-53 (the preferred polyol is 25 sucrose); Rizzi at page 398, "Materials" (sucrose); and Takagishi

translation at page 2 and 6 (sucrose). For methyl esters of fatty acid, see, Volpenhein at column 4, lines 2-5 and illustrating methyl ester of soybean oil in Example 1; Rizzi et al at page 398 under subheading "Materials"; and Takagishi at 5 Example 1 and page 5.

With respect to the transesterification catalyst, Volpenhein's preferred first stage and Takagishi's process use the same catalyst, i.e. potassium carbonate. See Volpenhein at column 4, lines 29 and 30 and Examples I and II; Takagishi 10 translation, page 5 and Example 1. Although Rizzi et al use sodium potassium alloy or sodium hydride as catalysts (see page 398, 2nd column), "Materials"), Volpenhein teaches that those materials are also suitable for use as equivalents to potassium carbonate (see Volpenhein Reference at column 4, lines 20 and 15 21).

With respect to the emulsifier, both Volpenhein and Rizzi use an alkali metal soap (Volpenhein at column 4, lines 6-19; Rizzi et al at page 398, under "Material") while Takagishi uses partial sucrose fatty acid esters because, he says, those esters 20 are preferable to using a fatty acid soap (see Takagishi translation at pages 3 and 4). It is well understood in the art that many types of emulsifiers may be used and are interchangeable in the transesterification reaction of sucrose and fatty acid lower esters in order to solubilize the sucrose 25 and improve the contact of the reactants. See, e.g., European

Patent Application No. 254,376 at page 3, lines 22-25 which discloses that "many types of alkali-resistant emulsifiers can be used to improve contact of ingredients in the reaction of sucrose and fatty acid lower esters to partial sucrose fatty acid esters.

5 Known edible emulsifiers include...soaps...and partial sugar esters of fatty acids."

Volpenhein's first stage, Rizzi et al's first stage and Takagishi's processes all operate at the same temperature and pressure. For temperature, see, Volpenhein at col. 5, line 14-16 (temperature range is 110 to 180°C with preferred temperature between 130 and 145°C); Rizzi et al at page 399, under "Sucrose/ME/Soap Reactions" (temperature at 150°C); and Takagishi's Example 1 (temperature at 140°C). For pressure, see, Volpenhein at column 5, lines 17-19 (preferred pressure range between 0.5 mm to 25 mm Hg); Rizzi et al at page 399, "Sucrose/ME/Soap Reactions" (pressure at 8 mm Hg) and Takagishi's Example (20 mm Hg).

With respect to operating the Takagishi's process in a separate "reaction zone" from Rizzi et al's and Volpenhein's second stage processes, it is well understood in the art that a 20 continuous process must inherently be operated in a separate reaction vessel from a subsequent reaction zone. Any other situation would preclude a continuous operation because if a subsequent stage of the reaction were attempted in the same continuous reaction zone, the subsequent stage would necessarily 25 destroy the steady state, mass balance required in a continuous

process. Thus, in a two stage reaction that involves a continuous first stage as taught by Takagishi and a second stage as taught by either Rizzi et al or Volpenhein, the second stage must necessarily take place in separate reaction zones. See,
5 e.g., Chemical Reaction Engineering, 2nd Ed. by Levenspiel (Wiley & Sons, 1972) at pages 97-98.

Hence, in light of Takagishi's Patent publication's teaching of a continuous transesterification process with operating conditions including reactants identical to Rizzi et al's and
10 Volpenhein's first stage, and yielding a reaction product substantially the same as Rizzi et al's and Volpenhein's first stage reaction products, i.e., partial sucrose fatty acid esters, it would have been obvious to a person having ordinary skill in the art to run the first stage of the Volpenhein or Rizzi et al process in a continuous manner and to thereafter continue the
15 reaction with Rizzi et al's or Volpenhein's second stage. See,
In re O'Farrell, 7 USPQ 2d 1673, 1681 (Fed. Cir. 1988) (obviousness, under 35 U.S.C. §103, "does not require absolute predictability of success...all that is required is a reasonable expectation of success"). Thus, the subject matter of the instant application would have been obvious to a person of ordinary skill in the art and is thus unpatentable under 35 U.S.C. §103.

It would have been obvious to one having ordinary skill in
25 the art at the time the invention was made having the Rizzi et

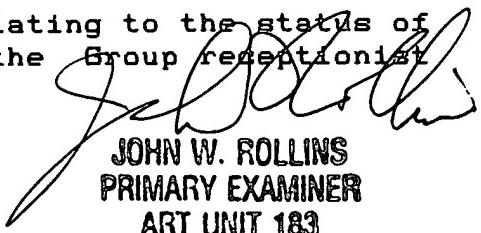
al, Volpenhein and Takagishi References before him to produce a process for preparing polyol fatty-acid esters which is operated in a continuous manner by reacting a polyol and a fatty-acid lower-alkyl ester under substantially solvent free conditions in 5 the presence of a transesterification catalyst and an emulsifier, with further limitations which involve the use of partial sucrose esters of fatty acids as taught in the European Patent Application No. 254,376, a limitation which involves a continuous operation which is further supported by the Felder et al and 10 McCabe & Smith References, the limitation which involves the second stage being carried out in separate reaction zones as taught by Levenspiel, since the European Patent Application No. 254,376, McCabe and Smith, Felder et al, and Levenspiel show that such limitations used in a process for preparing polyol fatty- 15 acid esters are well known in the art.

All the claims (1-6, 8-11, 13-15, 17, 18, 22-24, 27-32, 40-45, 48-51, 54-58 and 62-78) are rejected.

20 Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. White whose telephone number is (703) 308-4621.

25 Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

EW
White:ew
June 17, 1994


JOHN W. ROLLINS
PRIMARY EXAMINER
ART UNIT 183

APPENDIX A

5 Calculation of Molar Ratio of Sodium Oleate to Sucrose in the
Fuege Patent

10 The Fuege Patent at Col. 4, line 70 teaches percentages of sodium oleate based on the weight of 10%, 20% and 30% respectively. At col. 5, line 28, the patent teaches a maximum percentage of 40%.

15 a. molar ratio using teaching of 10% sodium oleate based
on weight of sucrose:

20 This percentage is equivalent to one gram of sodium oleate per 10 grams of sucrose. The one gram and the ten grams can be converted to moles and a ratio determined.

25
$$(1 \text{ gm sodium oleate})(1 \text{ mole sodium oleate} - 305 \text{ gm sodium oleate}) \\ = 0.0033 \text{ mole sodium oleate}$$

30
$$(10 \text{ gm sucrose}) (1 \text{ mole sucrose} - 342.5 \text{ gm sucrose}) \\ = 0.0292 \text{ mole sucrose}$$

Molar ratio of sodium oleate to sucrose: 0.11 : 1

35 b. molar ratio using teaching of 40% sodium oleate based
on weight of sucrose:

40 Converting 4 grams of sodium oleate per 10 grams of sucrose to a molar ratio:

45
$$(4 \text{ gm sodium oleate})(1 \text{ mole sodium oleate} - 305 \text{ gm sodium oleate}) \\ = 0.0131 \text{ moles sodium oleate}$$

50
$$(10 \text{ gm sucrose}) (1 \text{ mole sucrose} - 342.5 \text{ gm sucrose}) \\ = 0.0292 \text{ moles sucrose}$$

Molar ratio of sodium oleate to sucrose: 0.45 : 1

APPENDIX B

5 Calculation of "% polyol conversion" (as defined by the 438 patent) for n = 7.25 As shown at page 398 of the Rizzi Article

10 a. n is defined in the Rizzi article at page 398 as the "degree of esterification in isolated SPE." Thus, since sucrose has eight available hydroxyl groups that can be esterified, n of 8 is equivalent to a 100% "polyol conversion" (as defined by the '438 patent).

15 b. If n is 7.25, the "polyol conversion" is calculated:

$$\begin{aligned} & (7.25 \text{ moles OH esterified}) \div \\ & (8 \text{ moles OH available per mole sucrose}) \times 100 \\ & \qquad \qquad \qquad = 90.6 \% \text{ polyol conversion} \end{aligned}$$